UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, AND THE DISTRICT OF COLUMBIA, *ex rel.* MARY BIXLER WOOD,

Plaintiffs,

v.

SIEMENS MEDICAL SOLUTIONS USA, INC., SIEMENS HEALTHCARE DIAGNOSTICS, INC., AND SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH,

Defendants.

MEMORANDUM & ORDER
21-CV-1947 (MKB)

MARGO K. BRODIE, United States District Judge:

Plaintiff-Relator Mary Bixler Wood ("Relator"), acting on behalf of the United States of America, thirty states, and the District of Columbia, commenced the above-captioned action on April 12, 2021, against Defendants Siemens Medical Solutions USA, Inc., Siemens Healthcare Diagnostics, Inc., and Siemens Healthcare Diagnostics Products GmbH (collectively, "Defendants"). (Compl., Docket Entry No. 1.) The United States declined to intervene, and the

Court ordered the Complaint to be unsealed and served upon Defendants.[1] (Order dated Dec. 14, 2021, Docket Entry No. 4.) On March 29, 2022, Relator filed an Amended Complaint alleging that Defendants violated provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA") barring the presentation of false claims, the use of false statements, and conspiracies to violate the FCA as well as various state law FCA analogs.[2] (Am. Compl., Docket Entry No. 8.) On November 17, 2023, Relator filed a Second Amended Complaint, omitting Siemens Healthcare Diagnostics Products GmbH, and alleging identical FCA and state law claims against Siemens

[1] By stipulation dated June 15, 2021, Relator and the United States agreed to allow the United States until December 10, 2021 to determine whether to intervene in this action. (Stip. & Order, Docket Entry No. 3.)

[2] Relator claimed that Defendants violated the California False Claims Act, Cal. Gov't Code § 12650 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*; the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301 *et seq.*; the Delaware False Claims and Reporting Act, Del. Code. Ann. tit. 6, § 1201 *et seq.*; the District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq.*; the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat § 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*; the Iowa False Claims Act, Iowa Code § 685 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws. ch. 12, § 5A *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61-a *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act and Fraud Against Taxpayers Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and § 44-9-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. § 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. § 36.002 *et seq.*; the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; and the Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.005 *et seq.*

Medical Solutions USA, Inc. and Siemens Healthcare Diagnostics, Inc. [3] (Second Am. Compl. ("SAC"), Docket Entry No. 43.)

On March 12, 2024, Defendants moved to dismiss the SAC pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and Relator opposed.[4] For the reasons set forth below, the Court grants Defendants' motion and dismisses the Second Amended Complaint.

I. Background

The Court assumes the truth of the factual allegations in the SAC for the purposes of this Memorandum and Order.

a. The parties

From May of 2014 to December of 2015, Relator served as "Director of Compliance for a Siemens contractor that performed special projects for Siemens, including a project designed to qualify the shipping containers used by Siemens to maintain the temperature requirements during transport of the medical devices." (SAC ¶ 10.) Between February 17, 2016 and April 29, 2016, "Relator served as a contract employee directly for Siemens as a Project Manager for implementation and management of cold chain transportation processes." (*Id.*)

Siemens Medical Solutions USA, Inc., which is the parent company of Siemens Healthcare Diagnostics, Inc., is a Delaware corporation conducting business in Malvern, Pennsylvania and operating a distribution center in Plainfield, Indiana "where all domestic

[3] On August 31, 2022, Defendants moved to dismiss the Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. (Defs.' Mot. to Dismiss, Docket Entry No. 25.) The Court dismissed the Amended Complaint and granted Relator leave to file a second amended complaint. (Sept. 2023 Decision, Docket Entry No. 34.)

[4] (Defs.' Mot. to Dismiss the SAC ("Defs.' Mot."), Docket Entry No. 51; Defs.' Mem. of Law in Supp. of Defs.' Mot. ("Defs.' Mem."), Docket Entry No. 52; Pl.'s Mem. in Opp'n to Defs.' Mot. ("Pl.'s Opp'n"), Docket Entry No. 56; Defs.' Reply Mem. in Supp. of Defs.' Mot. ("Defs.' Reply"), Docket Entry No. 54.)

Siemens IVD shipments originate." (*Id.* ¶ 11.) Siemens Healthcare Diagnostics, Inc., a wholly-owned subsidiary of Siemens Medical Solutions USA, Inc., is a California corporation conducting business in Tarrytown, New York which "is responsible for maintaining premarket approvals and 510(k) clearances for . . . medical devices . . . as well as for maintaining compliance with applicable regulatory controls, such as FDA's Quality System Regulations, relating to those devices." (*Id.* ¶ 12.)

b. In vitro diagnostic medical devices

In vitro diagnostic ("IVD") medical devices "are tests (frequently referred to as assays) which are performed on blood, saliva or tissue samples that can be used to monitor a person's overall health to help cure, treat or prevent disease as well as to identify patients who are likely to benefit from specific treatments or therapies." (*Id.* ¶ 2 (citations and internal quotation marks omitted).) "An IVD that cannot be relied upon to provide an accurate measurement pertaining to the very medical issue for which the test has been designed is, by definition, a materially defective product for which neither payment nor reimbursement may be required under law or contract." (*Id.* ¶ 3.) "Many . . . IVD medical devices are temperature-sensitive and, in many cases, must be maintained in a refrigerated or frozen condition until they are used." (*Id.* ¶ 4.) "An IVD's value in accurately measuring and detecting analytes or markers in the human body . . . cannot be maintained if the temperature conditions necessary to meet the IVD's design and performance specifications do not exist." (*Id.* ¶ 7.) The failure of IVDs "presents a serious public health risk" because "[f]aulty diagnostic tests could result in false-positives or false-negatives, thus causing misdiagnosis" which could "lead to deferred treatments, unnecessary treatments, death, and serious injuries, among other negative consequences." (*Id.* ¶ 104.)

c. Defendants' IVD business

"Siemens is among the largest IVD manufacturers in the world," and in 2015 "was the third largest IVD manufacturer globally and was the second leading IVD company, in terms of market share, in the United States." (*Id.* ¶ 77.) "Siemens IVDs are reimbursed by Federal Health Care Programs." (*Id.* ¶ 82.) "Siemens affirmatively contracts with a third party to provide government reimbursement information for its entire menu of IVDs through an online product called CodeMap." (*Id.*) "IVDs . . . are reimbursed by Federal Health Care programs on the assumption that the IVDs are reliable, safe and effective for medically necessary diagnosis and treatment." (*Id.* ¶ 84.) Siemens sells IVDs to the Department of Defense and the Department of Veteran Affairs. (*Id.* ¶ 85.) In addition, Siemens has had contracts for IVD products with the Department of Health and Human Services, the Department of the Air Force, the Federal Bureau of Prisons, and the Department of Navy. (*Id.* ¶ 89.) "Individual States also purchase Siemens IVDs for use by State laboratories and health systems." (*Id.* ¶ 93.)

"Many Siemens IVDs . . . are highly temperature-sensitive devices that must be maintained in a refrigerated or frozen condition in order to ensure reliability, safety and efficacy in clinical use." (*Id.* ¶ 99.) In internal memoranda, "Siemens has recognized that IVDs are sensitive to temperature changes and must be stored and shipped under specific controlled temperature conditions . . . to ensure product integrity is maintained throughout the distribution process." (*Id.* ¶ 101 (citations and internal quotation marks omitted).) Siemens conducts stress testing, exposing its devices to different temperatures "for particular defined intervals," "[t]o assess whether its devices may be exposed, even briefly, to various temperature ranges." (*Id.* ¶ 100.)

d. Allegations of misconduct

Relator contends that "for many years, Siemens has knowingly shipped temperature-sensitive IVDs well outside their FDA-approved or -cleared temperature ranges." (*Id.* ¶ 112.) Siemens IVDs, which are stored at and shipped from Plainfield, Indiana, (*id.* ¶ 116), "were cleared or approved by [the] FDA for specific temperature ranges," (*id.* ¶ 117). "The labels on Siemens IVDs include temperature storage requirements and representations about shelf life" which "are based on purported testing conducted under the temperature conditions cleared or approved by the FDA." (*Id.* ¶ 115.) "Upon information and belief, Siemens has not conducted stability testing to validate the accuracy of the information on its device labels." (*Id.*) "Siemens knows that the expiration and shelf life information on its devices is inaccurate" and, "to the extent Siemens conducted stability testing," such testing "demonstrated that certain devices either fail or are not safe and effective within the shelf life stated on the device labels." (*Id.*)

Siemens uses corrugated boxes lined with foam called "shippers" to ship IVDs. (*Id.* ¶ 119.) After orders are placed, Siemens IVDs are "placed in the shipper, labeled, packaged, and given to a carrier (such as FedEx, UPS, etc.) for distribution." (*Id.* ¶ 118.) During the shipping process, IVDs "are not kept within temperature-controlled storage conditions" and "are removed from temperature-controlled storage conditions up to hours at a time in order to be packaged for shipment." (*Id.*) Siemens is aware from its field tests that its "shipped IVD devices reach temperatures well outside their approved or cleared temperature ranges." (*Id.* ¶ 121.) Between 2009 and 2015, Siemens hired companies to perform testing that showed that shippers Siemens used "failed to maintain devices within required temperature ranges." (*Id.* ¶ 122.) Tests conducted in 2009, 2010, 2012, and 2014 showed that shippers failed to maintain internal temperatures between two and eight degrees Celsius over a standard shipping time. (*Id.* ¶¶ 125–

26.) "Siemens was aware since at least 2009 that the shippers used by the company to transport IVDs to customers resulted in exposure of IVDs to temperatures well outside of their FDA-approved frozen or refrigerated ranges, rendering the shipped devices both adulterated and misbranded, with no assurances or reliability, safety or efficacy." (*Id.* ¶ 141.) "Siemens is fully cognizant of the safety risks that non-compliant temperature conditions create for its IVD products generally." (*Id.* ¶ 155.)

Relator also contends that Siemens caused others to submit false claims, which "did not disclose . . . the compromised reliability, safety and efficacy of the IVDs resulting from Siemens' non-compliance with FDA medical device laws and regulations," to Federal Health Care Programs for the use of its compromised IVD products. (*Id.* ¶ 189.) "Siemens also sold those compromised IVD products directly to the Government." (*Id.* ¶ 190.)

II. Discussion

a. Standard of review

In reviewing a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court "must construe [the Complaint] liberally, accepting all factual allegations therein as true and drawing all reasonable inferences in the plaintiff['s] favor." *Sacerdote v. N.Y. Univ.*, 9 F.4th 95, 106–07 (2d Cir. 2021) (citing *Palin v. N.Y. Times Co.*, 940 F.3d 804, 809 (2d Cir. 2019)); *see also Vaughn v. Phoenix House N.Y. Inc.*, 957 F.3d 141, 145 (2d Cir. 2020) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002)). A complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Bacon v. Phelps*, 961 F.3d 533, 540 (2d Cir. 2020) (quoting *Twombly*, 550 U.S. at 570). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct

alleged." *Matson v. Bd. of Educ.*, 631 F.3d 57, 63 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *see also Roe v. St. John's Univ.*, 91 F.4th 643, 651 (2d Cir. 2024) (quoting *Matson*, 631 F.3d at 63); *Cavello Bay Reinsurance Ltd. v. Shubin Stein*, 986 F.3d 161, 165 (2d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). Although all allegations contained in the complaint are assumed to be true, this tenet is "inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678; *Roe*, 91 F.4th at 651 ("Although all factual allegations contained in the complaint are assumed to be true, this rule does not extend 'to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.'" (quoting *Iqbal*, 556 U.S. at 678)).

b. Relator's FCA claims

Defendants argue that the SAC should be dismissed because Relator has failed to allege a false claim or a conspiracy to commit a false claim. (Defs.' Mem. 1, 4.) In support, Defendants argue first, that the allegations in the SAC have not remedied the Court's prior conclusion that Relator has failed to plead her claims with the requisite particularity required under Rule 9(b). (*Id.* at 25.) Defendants argue that Relator "still failed to plead with particularity any facts showing that *any* of Siemens' IVDs were ever damaged due to shipping conditions and then used to report results" or "any facts showing that *any* of Siemens' customers submitted 'actual false claims' to the government." (*Id.* at 25–26.) Second, Defendants argue that Relator cannot show that any claims were false. (*Id.* at 31.) They argue that Relator "fails to identify any certification that Siemens either made or caused to be made that was false." (*Id.* at 32.) Third, Defendants assert that Relator's allegations "fail[] to plead materiality." (*Id.* at 36.) Defendants argue that the government's "continu[ed] payment[s] and lack of action . . . following Relator's multiple [c]omplaints demonstrates that any issues raised by Relator are not a material consideration for

its continuing purchases and reimbursement." (*Id.* at 37.) Fourth, Defendants argue that Relator's claims are implausible on their face because the "the SAC lacks *any* facts supporting Relator's far-flung accusations." (*Id.* at 38.) Defendants assert that if Siemens had engaged in widespread fraud, Relator's complaint and record "would be rife with evidence of defective IVDs and shipments, voluminous customer complaints, myriad erroneous testing results and misdiagnoses, and ample data showing systemic problems." (*Id.* at 38–39.) Defendants also indicate that the SAC contains no allegations that the FDA brought enforcement actions against Siemens or directed Siemens to change its processes for shipping IVD products. (*Id.* at 39.) According to Defendants, the SAC contains "no such facts; because none exist . . . . It is not plausible that Relator (lacking any relevant IVD performance expertise) is the lone authority on how to ship IVDs in the U.S." and "Siemens, other manufacturers, labs, industry standard-setting bodies, the FDA, and the government are all getting it wrong." (*Id.*) Defendants also argue that Relator's conspiracy claims should be dismissed because "Relator has failed to plead an underlying FCA violation" and only alleges a conspiracy among employees and wholly-owned subsidiaries of the same corporation. (*Id.* at 39–40.)

Relator argues that she alleged specific evidence that eight Siemens IVDs were shipped outside of FDA-mandated temperature ranges, and the IVDs were thus "unreliable and unsafe as well as unreimbursable and unsaleable." (Pl.'s Opp'n 10.) In addition, Relator notes that she alleges "(1) that [Defendants'] shippers were incapable of maintaining required frozen and refrigerated temperature parameters for its IVDs; (2) that these thermal failures occurred within [Defendants'] average shipping times so that the actual shipment of misbranded/adulterated IVDs was assured;" and (3) Defendants were "well aware of these facts" and chose to continue shipping "IVDs in deficient shipping containers, thereby knowingly exposing numerous IVDs to

dangerous temperature excursions and rendering them adulterated and misbranded under the FCA." (*Id.* at 30.) Relator states that she "is not required . . . to identify specific IVD shipments exposed to non-compliant temperature excursions" prior to discovery because "she has otherwise alleged highly detailed and compelling facts establishing a general business practice which ensured that numerous IVDs were so exposed and that Siemens knew this to be true." (*Id.* at 31.) Relator also contends that she did allege that Defendants violated FDA regulations and submitted false claims. (*Id.* at 6, 11–12, 19, 20–27.) She "alleged specific facts concerning numerous Government contracts and purchases of Siemens IVDs . . . during the same period when [she] alleges that Siemens IVDs were misbranded/adulterated for failure to comply with FDA quality and marketing regulations governing temperature requirements," (*id.* at 6). In addition, Relator contends that her claims adequately allege materiality and are plausible. She argues that Siemens improperly asks the Court to "infer a lack of merit" in Relator's claims based on the government's decision not to join the case and the government's continued payments for Siemens IVDs and lack of enforcement actions against Siemens for allegedly improperly shipping the IVDs. (*Id.* at 11–12.) Relator further argues that her claims are plausible because Siemens knowingly failed "to ship its IVDs in temperature-controlled environments" as required by federal regulations and thus "violat[ed] a bevy of FDA quality and marketing regulations and rendering the IVDs misbranded/adulterated." (*Id.* at 19.) Relator also argues that she adequately pleaded a conspiracy claim and that the intra-corporate doctrine is inapplicable because she has alleged conduct constituting a criminal conspiracy. (*Id.* at 39–40.)

The FCA provides that "'a private plaintiff, known as a relator,' may 'bring[] suit on behalf of the [g]overnment to recovery a remedy for a harm done to the [g]overnment.'" *United States ex rel. Camburn v. Novartis Pharms. Corp.*, --- F.4th ---, 2024 WL 5230128, at *1 n.1 (2d

Cir. Dec. 27, 2024) (alterations in original) (citation omitted); *United States ex rel. Yu v. Grifols USA, LLC*, No. 22- 107, 2022 WL 7785044, at *1 n.1 (2d Cir. Oct. 14, 2022) (citing 31 U.S.C. § 3730(b)(1)). The FCA imposes liability for, among other things, "knowingly" presenting or causing to be presented "a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A); *Camburn*, 2024 WL 5230128, at *4 ("The FCA proscribes individuals from 'knowingly . . . caus[ing] to be presented[] a false or fraudulent claim for payment or approval'" (alterations in original) (quoting 31 U.S.C. § 3729(a)(1)(A)–(B))); *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 152 n.3 (2d Cir. 2024) ("The FCA prohibits, as relevant here, 'knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval' to the federal government" (alterations in original) (quoting 31 U.S.C. § 3729(a)(1)(A))); *Doe 1 v. EviCore Healthcare MSI, LLC*, No. 22-530, 2023 WL 2249577, at *2 (2d Cir. Feb. 28, 2023) ("The FCA imposes liability on 'any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.'" (alterations in original) (quoting 31 U.S.C. § 3729(a)(1)(A))); *Lee v. N. Metro. Found. for Healthcare, Inc.*, No. 21- 2155, 2022 WL 17366627, at *1 (2d Cir. Dec. 2, 2022) (quoting same). "FCA liability can be premised on 'specific representations about the goods or services provided' which, while not expressly false, 'fail[] to disclose noncompliance with material statutory, regulatory, or contractual requirements.'" *Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 78–79 (2d Cir. 2022) (alterations in original) (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016)); *Fed. Deposit Ins. Corp. v. Fifth Third Bank, N.A.*, No. 23-209, 2023 WL 7130553, at *2 (2d Cir. Oct. 30, 2023) (stating that an FCA claim "does not require an 'express falsehood[],' and can rely on 'misrepresentations by omission . . . [but] still must 'make[] specific representations about the goods or services provided'" (alterations in

original) (quoting *Escobar*, 579 U.S. at 187, 190)). Although Congress has repeatedly amended the FCA, "its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Escobar*, 579 U.S. at 182; *see also United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 424 (2023) ("The Act . . . impose[s] civil liability for many deceptive practices meant to appropriate government assets."); *United States v. Wells Fargo & Co.*, 943 F.3d 588, 596 (2d Cir. 2019) ("[T]he objective of Congress was broadly to protect the funds and property of the Government from fraudulent claims, *regardless of the particular form, or function*, of the government instrumentality upon which such claims were made." (quoting *Rainwater v. United States*, 356 U.S. 590, 592 (1958))). "A 'claim' . . . includes direct requests to the [g]overnment for payment as well as" claims for reimbursement under federal benefits programs. *Escobar*, 579 U.S. at 182 (citation omitted). "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material* to the [g]overnment's payment decision in order to be actionable under the False Claims Act." *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 109 (2d Cir. 2021) (quoting *Escobar*, 579 U.S. at 181).

"Qui tam complaints filed under the FCA, because they are claims of fraud, are subject to Rule 9(b)." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Resp., Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (citing *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016), and *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476–77 (2d Cir. 1995)); *see also Miller v. United States ex rel. Miller*, 110 F.4th 533, 543 (2d Cir. 2024) ("[C]laims under the FCA . . . are subject to the heightened pleading standard found in Federal Rule of Civil Procedure 9(b)." (citing *Foreman*, 19 F.4th at 119)). "Rule 9(b) requires that '[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or

mistake.'" *Camburn*, 2024 WL 5230128, at *3 (alteration in original) (quoting Fed. R. Civ. P. 9(b)); *Ladas*, 824 F.3d at 25 (same); *Grifols*, 2022 WL 7785044, at *2 (same). "Under Rule 9(b), the party alleging fraud must: '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Doe 1*, 2023 WL 2249577, at *2 (quoting *Chorches*, 865 F.3d at 81). In other words, Rule 9(b) "requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *HDtracks.com, LLC v. 7digital Grp. PLC*, No. 18-CV-5823, 2019 WL 6170838, at *10 (S.D.N.Y. Nov. 19, 2019) (quoting *Minnie Rose LLC v. Yu*, 169 F. Supp. 3d 504, 511 (S.D.N.Y. 2016)). As the Second Circuit has explained, "Rule 9(b) serves several purposes. '[I]t is designed to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from "improvident charges of wrongdoing," and to protect a defendant against the institution of a strike suit.'" *Miller*, 110 F.4th at 544 (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)). "It also discourages plaintiffs from using the litigation process to discover hypothetical wrongdoing." *Id.* (citing *Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989)). "'Bare-bones allegations' therefore do not suffice." *McNaughton v. Young Living Essential Oils, LC*, 67 F.4th 89, 99 (2d Cir. 2023) (quoting *Lundy v. Cath. Health Sys. of Long Island Inc.*, 711 F.3d 106, 119 (2d Cir. 2013)).

"[T]o survive dismissal under Rule 9(b) when the complaint pleads only on information and belief that fraudulent claims were actually submitted to the United States, a plaintiff must (1) 'make plausible allegations that the bills or invoices actually submitted to the government were uniquely within [the defendant's] knowledge and control,' and (2) 'adduce specific facts supporting a strong inference of fraud.'" *United States ex rel. Gelbman v. City of New York*, 790

F. App'x 244, 248 (2d Cir. 2019) (alterations in original) (quoting *Chorches*, 865 F.3d at 83); *see also Camburn*, 2024 WL 5230128, at *3 (explaining that relator "was obligated to 'plead the factual basis' that 'gives rise to a strong inference of fraudulent intent'" under Rule 9(b) (quoting *Hart*, 96 F.4th at 153)); *United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020) ("'Rule 9(b) permits knowledge to be averred generally,' but plaintiffs . . . still must 'plead the factual basis which gives rise to a strong inference of fraudulent intent.'" (quoting *O'Brien*, 936 F.2d at 676)); *Chorches*, 865 F.3d at 86 ("[A] complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge.").

Relator's allegations in the SAC fail to satisfy Rule 9(b)'s particularity requirement. Relator asks the Court to presume that the IVDs she identified in the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database malfunctioned due to storage or shipping conditions. (SAC ¶¶ 171–79.) Relator's allegations, however, only indicate that the IVDs malfunctioned, but fail to specifically allege what caused the malfunctions. (*Id.*) Relator also fails to allege that any of Siemens' customers actually submitted false claims to the government. Relator alleges that according to MAUDE, eight Siemens IVDs "collectively suffered *thousands of testing malfunctions*" throughout "the same period the tests were being reimbursed by Federal Health Care Programs and purchased directly by government agencies." (*Id.* ¶¶ 172–79.) Relator also contends that Defendants failed to comply with FDA regulations for "stor[ing] and shipp[ing IVDs] in refrigerated and/or frozen conditions," (*id.* ¶ 172), meaning that Defendants' shipping practices "render[ed] the IVDs adulterated and misbranded, severely comprise[d] their reliability and efficacy, and jeopardize[d] patient health," (*id.* ¶ 121). Relator alleges that

Defendants' shipping practices caused others to submit false claims to the federal and state governments which "did not disclose . . . the compromised reliability, safety and efficacy of the IVDs" stemming from their "non-compliance with FDA medical device laws and regulations." (*Id.* ¶ 189.) These allegations, absent specific contentions that the eight IVDs Relator identified malfunctioned as a result of Siemens' storage or shipping practices, fail to satisfy Rule 9(b)'s particularity requirement. *See Conte v. Kingston NH Operations LLC*, 585 F. Supp. 3d 218, 239 (N.D.N.Y. 2022) (holding that plaintiff did not satisfy Rule 9(b) by "merely stat[ing] a set of circumstances and ask[ing] the [c]ourt to connect the dots by assuming that [d]efendant submitted false claims"); *Ladas*, 824 F.3d at 26–28 (upholding a district court's holding that plaintiff did not satisfy Rule 9(b) by presenting "hypotheses" about the condition of products sold to the government rather than sufficient "factual allegation[s] concerning the actual condition of the equipment upon or after the delivery to the government"). In addition, Relator's failure to allege that Defendants' shipping practices compromised any IVDs for which claims to governments were actually submitted is fatal to her FCA claim. *See United States ex rel. Pepe v. Fresenius Med. Care Holdings*, No. 14-CV-3505, 2024 WL 4635236, at *5 (E.D.N.Y. Oct. 31, 2024) (dismissing FCA claims where plaintiff did not plead "any facts connecting the alleged conduct to 'specific claims [that] were indeed submitted' to the government" (quoting *Chorches*, 865 F.3d at 93)); *Miller*, 110 F.4th at 548 (upholding a district court's finding that plaintiff failed to satisfy Rule 9(b)'s particularity requirement because she "did not identify any specific statement, record, or report that was falsified or withheld from the government"); *United States ex rel. Powell v. Medtronic, Inc.*, No. 18-CV-1628, 2024 WL 4165522, at *6–10 (S.D.N.Y. Sept. 12, 2024) (finding that the plaintiff did not satisfy Rule 9(b) because "she has not identified any actual false claims that were submitted to a government payor"); *Conte*, 585 F. Supp. 3d at 239

(finding that the plaintiff failed to satisfy Rule 9(b) because she did "not allege[] facts plausibly suggesting how a particular submitted claim is false or fraudulent"); *United States ex rel. Duhaine v. Apple Health Care Inc.*, No. 19-CV-963, 2022 WL 3226631, at *6, *9 (D. Conn. Aug. 10, 2022) (granting a motion to dismiss where relator did not provide "any stated reason for [her] belief that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the [g]overnment" (quoting *United States ex rel. Clausen v. Lab'y Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)); *Ping Chen ex rel. United States v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 302 (S.D.N.Y. 2013) (finding that plaintiff failed to satisfy Rule 9(b) because he did not "identify a particular false claim that was submitted to the government for payment by any [d]efendant"); *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 268 (W.D.N.Y. 2010) (finding Rule 9(b) unsatisfied where plaintiffs did not "identif[y] any particular case where a fraudulent bill was presented"). Accordingly, the Court dismisses Relator's FCA claims.

Given that the Court dismisses Relator's FCA claims, the Court also dismisses Relator's FCA conspiracy claim. *See Ladas*, 824 F.3d at 27–28 (affirming a district court's dismissal of a "claim of conspiracy to violate the FCA" because the complaint "fail[ed] to identify a specific statement where [defendants] agreed to defraud the government" (citation omitted); *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 50 (2d Cir. 2016) ("[T]he relators cannot show a conspiracy to commit fraud given that they have not sufficiently pleaded fraud under the FCA."), *cert. granted, judgment vacated on other grounds*, 580 U.S. 1108 (2017); *United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 551 F. Supp. 3d 27, 48 (E.D.N.Y. 2021) ("Relator has failed to state a claim for violation of the FCA . . . and so [r]elator's conspiracy claim must also be dismissed"), *aff'd*, No. 21-2117, 2022 WL 17818587 (2d Cir. Dec. 20, 2022); *United*

States v. Strock, No. 15-CV-887, 2018 WL 647471, at *12 n.7 (W.D.N.Y. Jan. 31, 2018) ("Plaintiff's FCA conspiracy claim fails for the separate reason that a plaintiff cannot allege a conspiracy to commit an FCA violation when it has failed to adequately allege an underlying violation of the statute.").

c. Relator's state law claims

Because the Court dismisses Relator's FCA claims, the Court declines to exercise supplemental jurisdiction over Relator's state law claims. *Garrasi v. Wells Fargo Bank, N.A.*, 2024 WL 191802, at *2 (2d Cir. Jan. 18, 2024) (upholding a district court's dismissal of state law claim where the court also dismissed plaintiff's federal claim (citing *Kolari v. N.Y.-Presbyterian Hosp.*, 455 F.3d 118, 122 (2d Cir. 2006))); *Fernandez v. Zoni Language Ctrs., Inc.*, 858 F.3d 45, 46 n.1 (2d Cir. 2017) (affirming district court's decision declining to exercise supplemental jurisdiction over state law claims after dismissing plaintiffs' federal claims); *All. of Auto. Mfrs., Inc. v. Currey*, 610 F. App'x 10, 14 (2d Cir. 2015) (holding it was "not improper for the court to decline to exercise its supplemental jurisdiction" after it properly dismissed the plaintiff's federal claims); *One Commc'ns Corp. v. J.P. Morgan SBIC LLC*, 381 F. App'x 75, 82 (2d Cir. 2010) ("If all of a plaintiff's federal claims are dismissed, a district court is well within its discretion to decline to assert supplemental jurisdiction over any state law claims[.]" (citing *WWBITV, Inc. v. Vill. of Rouses Point*, 589 F.3d 46, 52 (2d Cir. 2009))). Accordingly, the Court dismisses without prejudice Plaintiff's state law claims.

III. Leave to Amend

Relator argues that if the Court dismisses her SAC, the Court should grant her leave to amend her pleadings a second time. First, Relator argues that the Court's decision on her SAC is "just the *second* time that a court — *any court* — has had an opportunity to assess the adequacy

of Relator's allegations," rather than Relator's fifth attempt, as Defendants argue. (Pl.'s Opp'n 40.) Second, Relator argues that permitting her to amend her pleadings again would not be "futile" which is the only "narrow exception" for denying amendment. (*Id.*) Relator requests leave to amend "in order to satisfy whatever concerns the Court may continue to have." (*Id.*)

Defendants argue that further amendments "will not cure the fundamental deficiencies" in Relator's claims. (Defs.' Mem. 20.) They argue that Relator "does not say what additional factual allegations she would make" and that, after "eight years of trying," Relator "has demonstrated that she simply cannot plead a viable claim against Siemens." (*Id.*)

The Court grants Relator's request for leave to file a third amended complaint. *See, e.g., Fraser v. City of New York*, No. 20-CV-5741, 2022 WL 3045524, at *10 (E.D.N.Y. Aug. 1, 2022) (permitting plaintiff leave to file an amended complaint where "the record d[id] not indicate that she ha[d] repeatedly submitted deficient pleadings"); *Ladas*, 824 F.3d at 28 (noting that Rule 15 of the Federal Rules of Civil Procedure provides that "[l]eave to amend should be 'freely give[n] . . . when justice so requires,' but 'should generally be denied in instances of futility, undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or undue prejudice to the non-moving party'" (second and third alterations in original) (first quoting Fed. R. Civ. P. 15(a)(2); and then quoting *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 126 (2d Cir. 2008))); *see also Meyer v. Seidel*, 89 F.4th 117, 139 (2d Cir. 2023) (noting that leave to amend should be freely given). Because leave to amend should be freely given under Rule 15 of the Federal Rules of Civil Procedure, the Court grants Relator leave to file a third amended complaint. The Court also grants Relator leave to refile her state law claims if she refiles her FCA claims.

IV. Conclusion

For the reasons stated above, the Court grants Defendants' motion and dismisses Relator's claims without prejudice. The Court grants Relator leave to file a third amended complaint. Any third amended complaint must be filed within thirty days from the filing of this Memorandum and Order. If a third amended complaint is not timely filed, the Court will direct the Clerk of Court to enter judgment and close this case.

Dated: January 17, 2025
Brooklyn, New York

SO ORDERED:

/s MKB
MARGO K. BRODIE
United States District Judge